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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,793	12/15/2005	Xiangsheng Meng	CGL03/0043US01	7410
46395 7590 12/10/2007 CARGILL, INCORPORATED LAW DEPARTMENT P. O. BOX 5624 MINNEAPOLIS, MN 55440-5624			EXAMINER KATAKAM, SUDHAKAR	
			ART UNIT 1621	PAPER NUMBER
			MAIL DATE 12/10/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,793	Applicant(s) MENG ET AL.	
	Examiner Sudhakar Katakam	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/01/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

1. Receipt of applicant's request for continued examination filed on 22nd Oct 2007 and remarks/arguments filed on 2nd Oct 2007 is acknowledged. Applicant's arguments with respect to claims 1-17 have been considered but are moot in view of the new ground(s) of rejection. The claims 1-17 remain rejected and all claims are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim 4 recite "3-hydroxypropionic acid recovered is at least about 80% pure", but the specification does not appear to support for this matter. This is new matter. See *Ex parte Stiles et. al.*, 125 USPQ 661. It must be shown that reaction conditions added by amendment necessarily must result in order for their addition to the disclosure not to constitute new matter.

4. Claims 1-2, 4-12, and 14-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the process comprising separating

and recovering 3-hydroxypropionic acid from an aqueous solution comprising 3-hydroxypropionic acid and acrylic acid using specific solvents exemplified in the examples, does not reasonably provide enablement for all of applicants broadly claimed solvents.

There are eight factors to be considered in determining whether undue experimentation is required, are summarized by the Federal Circuit in the determination of undue experimentation, *In re Wands*, 8 USPQ 2nd 1400 (1988). These factors are:

1. The nature of the invention,
2. The state of the prior art,
3. The predictability or lack thereof in the art,
4. The amount of direction or guidance present,
5. The presence or absence of working examples,
6. The breadth of the claims,
7. The quantity of experimentation needed, and
8. The level of the skill in the art.

The examiner will discuss these factors as they apply to the instant invention.

(1). **Nature of the invention:** The claimed invention is drawn to a process comprising separating and recovering 3-hydroxypropionic acid from an aqueous solution comprising 3-hydroxypropionic acid and acrylic acid using an organic extractant other than ethyl acetate, wherein organic extractant comprises an alcohol, an ether, an ester, a ketone, an amide, a phosphorus ester, a halogenated compound, an aromatic compound, a phosphine oxide, a phosphine sulfide, an alkyl sulfide, and mixtures thereof.

(2). **Breadth of the claims:** The claims are extremely broad. In particular claims read on all organic extractants other than ethyl acetate. The number of extractants

encompassed by the listed solvents is vast. The claims 3 and 13 recite a specific extractants for the process.

(3). **State of the Prior Art:** The prior art (GB 1,167,793 and acknowledged prior art in the specification page 1) teaches a process to separate acrylic acid, which the acrylic acid is separated practically quantitatively in a few extraction stages, in which the solvent need not be distilled, in which the addition of a salt to the aqueous phase is not necessary and in which the main impurities, i.e., propionic acid and acetic acid, can be easily separated [col.1, lines 65-74 & col.2, lines 1-3]. Acknowledged prior art in the specification in page 1 also teaches the known methods for separating 3-hydroxypropionic acid from an aqueous solution comprising 3-hydroxypropionic acid and acrylic acid.

(4). **Unpredictability of the Art:** A process for separating 3-hydroxypropionic acid from an aqueous solution comprising 3-hydroxypropionic acid and acrylic acid with an organic extractant other than ethyl acetate is speculative and unpredictable. There is no information provided regarding a predictable correlation between the solvents and the higher yield of the 3-hydroxypropionic acid. The organic solvent for extraction may be anything other than ethyl acetate, so long as it has a boiling point lower than about 100°C and allows for separation and recovery. There is no structure given here to provide any guidance regarding which of the many encompassed organic solvents would be expected to allow for separation and recovery and which would not. Furthermore, if patentability relies on high efficiency recovery, there is no guidance regarding which solvents will predictably give higher yield. The only example of a

solvent with a boiling point lower than 100°C is isopropyl ether. Further, the results on pages 11-12 indicate that all organic solvents are not equal in their extraction ability. Applicant has provided no explanation for why the differences are there and how to best choose an effective extractant.

(5). **Amount of Guidance Provided:** Applicants have provided no guidance for regarding which solvents will predictably give higher yield.

(6). **Presence or Absence of Working Examples:** There are only a small number of examples of "a process for separating 3-hydroxypropionic acid from an aqueous solution comprising 3-hydroxypropionic acid and acrylic acid with an organic extractant other than ethyl acetate" in applicants specification.

(7). **Ordinary Skill in the Art:** The ordinary skill in the art is high.

(8). **Amount of Experimentation Necessary:** In light of the state of art, the unpredictability of the art and amount of guidance provided, as discussed above, the amount of experimentation necessary to practice the current methods is undue. While one may expect to be able to separate 3-hydroxypropionic acid to some extent, one of ordinary skill in the art would have to perform experimentation to determine which extractants if any are effective in the process. One of skill in the art would then have to determine which if any process may be effectively treated by administration of the as yet unidentified active and effective extractant. One of skill in the art is provided with no guidance regarding selection of extractant, quantity etc. The amount of experimentation necessary to identify useful extractant in a form useful to treat the claimed invention is not routine.

Thus, it can safely be concluded that the instant disclosure fails to provide an enabling disclosure for the "process comprising separating and recovering 3-hydroxypropionic acid from an aqueous solution comprising 3-hydroxypropionic acid and acrylic acid using an organic extractant other than ethyl acetate".

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Combined teachings of the acknowledged prior art (see page 1 of specification), and **Badische Anilin- & Soda-Fabrik AG** (GB 1,167,793) taken with **Changzhou et al** (Huaxueshijie, 1997, 19(2), 77-79).

Acknowledged prior art relied on is that shown at the bottom of the page 1 of specification, where it is acknowledged that "Various methods for separating and recovering 3-hydroxypropionic acid from an aqueous solution comprising 3-

hydroxypropionic acid and acrylic acid are known. Included within such methods is distilling acrylic acid from the aqueous solution. Further, it is known that acrylic acid in the aqueous solution is extracted with ethyl acetate".

The difference between the instant claims and the acknowledged prior art is the "extractant". The instant claims are specific to the extractant other than ethyl acetate, whereas the acknowledged prior art is specific to ethyl acetate.

Badische Anilin- & Soda-Fabrik AG teach other solvents, such as lactam, but it also teaches the use of mixtures of solvents such as aliphatic, cycloaliphatic or aromatic hydrocarbons, halohydrocarbons, ethers or esters [col.2, lines 95-102], in the purification of acrylic acid which contains propionic acid impurity. The propionic acid and 3-hydroxypropionic acid differs from each other by a -OH group. Acrylic acid and 3-hydroxypropionic acid have the known partition coefficients of 0.35 and -0.89 (given as logP octanol/water, as found in customary handbooks). Therefore, 3-hydroxypropionic acid is known to be about 17 times more water-soluble than acrylic acid. The skilled artisan facing the problem to separate both acids present in a single aqueous solution would contemplate extracting the less water soluble, i.e. acrylic acid with an organic solvent. The use of a low boiling extractant is obvious for reasons of ease of recovery of acrylic acid, either as solid or as an aqueous solution.

Changzhou et al teach the formation of β -hydroxypropionic acid by hydration of acrylic acid at high temperature (see Abstract, translation of full text pending).

Please note the separation of organic acids from less water-soluble compounds is obvious in the art. The removal of the organic solvent by distillation for displacing the

compound to be extracted into water is a routine measure for the skilled artisan, especially when the said compound has a non-negligible solubility in the said organic solvent.

In view of explicit teachings of references and from the known separation methods in the art based on the compound physical properties, the examiner purports that it would have been obvious to a person of ordinary skill in the art, at the time of invention was made, to have modified the reference teachings in separation of 3-hydroxypropionic acid and acrylic acid, with a reasonable expectation of success.

Modifying such methodology is a prima facie obvious because an ordinary artisan would be motivated to use known purification methods to make the process more efficient or explore economical advantages over the other, since it is within the scope to optimize the conditions through routine experimentation.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over (i) the claims 1-17 of U.S. 7,279,598 in view of acknowledged prior art (see page 1 of specification), and **Badische Anilin- & Soda-Fabrik AG** (GB 1,167,793) taken with **Changzhou et al** (Huaxueshijie, 1997, 19(2), 77-79).

Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons:

The instant claims are drawn to a process comprising separating and recovering 3-hydroxypropionic acid from an aqueous solution comprising 3-hydroxypropionic acid and acrylic acid using an organic extractant other than ethyl acetate, wherein organic extractant comprises an alcohol, an ether, an ester, a ketone, an amide, a phosphorus ester, a halogenated compound, an aromatic compound, a phosphine oxide, a phosphine sulfide, an alkyl sulfide, and mixtures thereof.

The US 7,279,598 claims are drawn to a process for separating and recovering 3-hydroxypropionic acid from aqueous solution comprising 3-hydroxypropionic acid and acrylic acid, comprising counter current extracting the aqueous solution with ethyl acetate, to extract the acrylic acid from the aqueous solution into the organic phase, and

the resulted organic phase is heated in presence of water to distill off the ethyl acetate, thereby forming an aqueous acrylic acid solution.

The teachings of acknowledged prior art, **Badische Anilin- & Soda-Fabrik AG**, and **Changzhou et al** are as given above in 103 (a) rejection.

The difference between the instant claims and the US patent claims is the "extractant". The instant claims are specific to the extractant other than ethyl acetate, whereas US patent claims are specific to ethyl acetate. However, the references teach other solvents in the purification of acrylic acid.

Therefore, it would have been a prima facie obvious at the time the invention was made to one of ordinary skill in the art to start with the teachings of US patent with an alternative extractants, to make instant applicants' process and to expect to produce a separate 3-hydroxypropionic acid from acrylic acid with a reasonable expectation of success. Therefore, the difference does not constitute a patentable distinct, because the claims of the present invention comprises the solvents, such as esters, which includes methyl acetate, which is obvious over the ethyl acetate of US patent claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not been patented yet.

Conclusion

10. No claim is allowed in the absence of a showing of unexpected beneficial results commensurate in scope with the claims.

Application/Control Number:
10/560,793
Art Unit: 1621

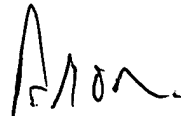
Page 11

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Katakam


PETER O'SULLIVAN
PRIMARY EXAMINER
DEC 7 1999